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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,606	01/21/1999	JON A. WOLFF	MIRUS.010	5854

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[REDACTED] EXAMINER

NGUYEN, DAVE TRONG

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

DATE MAILED: 10/02/2002

511

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/234,606	WOLFF ET AL.	
	Examiner	Art Unit	
	Dave Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 May 2001.
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1 and 3-13 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) _____ is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) 1 and 3-13 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: <i>detailed action</i> . |

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Claims 1, 3, 6-13 have been amended, claims 14-19 have been added by the amendment filed May 22, 2001.

Due to the newly added claims, Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1, 3-17, directed to a method of employing a chelator/polymer complex or a polychelator/polymer for delivering the polymer to a cell, classifiable in class 514, subclass 44.

Group II. Claims 18, directed to a method of removing chelators from a delivered chelator/polymer complex in an *in vivo* environment, classifiable in class 435, subclass 455.

Group III. Claim 19, directed to a method of employing an expressible polymer/non-expressible polymer wherein the non-expressible polymer has been chelated for the delivering of an expressible polymer to a cell, classifiable in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different materially step methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions I, II, and III are directed to different and materially distinct steps and goals, as indicated above.

The claimed invention of Group I is not necessarily limited for use in the invention of Group II and can used in a gene therapy method, wherein the removal step is not employed. The invention II does not require the presence of chelators after the *in vivo* delivery step as claimed in invention I. In addition, the invention III requires that the non-expressible polymer is chelated rather than the expressible polymer, whereas in invention I and II, what is required is the complex between a delivered and expressible polymer and a chelator or polychelator. Since Inventions I, II, and III comprise materially distinct steps, and/or generate different functions and effects, and thus, are not required for use together, it would also be unduly

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burdensome for the examiner to search and/or consider the patentability of all of the subject matter being sought in all of the pending claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER